Periodic
(21 CFR 1304.11)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day should be conducted, and a monthly count of all controlled substances in the facility.

When. Counts should be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count should be conducted as close to the same time each month as possible.

General Requirements

Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. **(21 CFR 1304.11 (d))**

> *Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.*

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

> *Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.*

Retention of Inventory Records. The record must be retained for two years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. **(21 CFR 1304.04)**

> *Note: State record keeping requirements may be more than two years and records should be maintained accordingly.*

DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

Prefix. 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). **(Refer to DEA Correspondence 8/25/93).** The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.").

Suffix. The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2nd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	B
February 28	S	August 31	C, E
March 31	L, P	September 30	F, G
April 30	Q, R, 9	October 31	H, N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	J, K, O

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current DEA **Certificate of Registration (Exhibit J).** DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license should be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration **(Exhibits K, L).** A copy of the state license should also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered.

Cardinal purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The **Quarterly DEA Exception Report (Exhibit N)** is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry should be made to ensure that the customer is properly registered. The local DEA office **will** check this type of situation. Calls to the local DEA office should be documented on a **Regulatory Agency Contact Form (Form #1).**

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler should contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler should write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a **Regulatory Agency Contact Form. Refer to DEA Correspondence 9/7/93.**

Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. **(21 CFR 1301.51)**

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a **Limited Power Of Attorney (Form #25)** that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you should obtain a copy of the **Power Of Attorney** and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy. **Refer to DEA Correspondence 8/25/93.**

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred,
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methampetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

Prefix. The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

Suffix. The suffix contains three alpha characters. The first is the first letter in the registrants name. The second is a random letter and the third identifies the activity of the registrant as listed below.

W - Manufacturer

Y - Distributor

V - Retail Distributor

X - Importer

Z - Exporter

ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - **DEA Form 222 (Exhibit O).** Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant **currently** is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers should be logged on the **DEA Narcotic Blank Log (Form #4),** and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms

(21 CFR 1305.06)

- The purchaser simultaneously prepares and executes order forms in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler may consider rejecting any Form 222 completed in pencil, indelible or not, as the identification of indelible over regular lead is tenuous at best.

- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid.

If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number should correspond to the number of lines used. For example, if two lines are used on an order form to describe one item, the number of lines completed at the bottom is two.

- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form should show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.

- The correct name and address of the supplier from whom the controlled substances are being ordered is entered on the form. Only one supplier may be listed on any one form.

- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to **21CFR 1305.05(c)**. The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

- Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

  Note: All 222 Requisition Forms received by the divisions should be forwarded to Corporate Purchasing.

- Order Form Books are received at the division.
- The division logs the order form numbers onto the **DEA Narcotic Blank Log.**
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the **DEA Narcotic Blank Log.**
- Corporate Purchasing receives and stores order forms in a secure area. Corporate Purchasing contacts division if numbers are out of sequence or an order form is missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations **(21 CFR 1305.06).**
- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor; Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

  Note: All three copies of voided order forms must be sent to the division.
- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto **DEA Narcotic Blank Log**. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney

(21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a **Power of Attorney (Form #2)** for each such individual. The **Power Of Attorney** is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney should be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a **Notice Of Revocation (Form #3),** signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

Sales of Schedule I and II Substances

Procedure for Filling Order Forms

(21 CFR 1305.09)

- The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

  Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver should have no knowledge of the contents of the order form. ***Refer to DEA Correspondence 07-18-96.***

- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies 1 (brown) and 2 (green) the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.

- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.

- The supplier retains copy 1(brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

  Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

  Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution. **Refer to DEA Correspondence 6/29/92.**

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.
- The order forms and a **DEA 222 Transmission Log (Form #5)** are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are **not** released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure **shall not be used unless** the depot operation is supervised by a Cardinal employee, the Cardinal employee faxes the order forms, and the Cardinal employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA **will not permit**, under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees. **Refer to DEA Correspondence 07-18-96 and 08-28-96.**

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

1. Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.

2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal crossdock employee.

3. Cardinal crossdock employee removes 222s from envelopes and completes **DEA222 Transmission Log** (Form #5).

4. Cardinal employee faxes 222s to distribution center. **This should be done using one transmission and the DEA222 Transmission Log should be the last page of the fax.**

5. Fax is received in distribution center by Operations Manager or designee.

6. Operations Manager or designee verifies faxed 222s received with information on the DEA 222 Transmission Log. Faxed copies of 222s are checked for legibility and compliance and are processed according to DEA regulations.

    a) If any discrepancies exist that would require 222s to be re-faxed, Operations Manager or designee contacts Cardinal crossdock employee.

7. Cardinal crossdock employee places original 222s in a sealed envelope for delivery to the distribution center.

8. Operations Manager or designee delivers faxed 222s to the vault.

9. Vault clerk fills orders and files faxed 222s. Orders are held until original 222s arrive at the distribution center and are compared to the orders.

FROM THE CUSTOMER:

1. Customer faxes 222 directly to the distribution center.

2. Operations Manager or designee checks 222 for legibility and compliance and processes according to DEA regulations.

a) If any discrepancies exist that would require 222 to be re-faxed, Operations Manager or designee contracts the customer.

3. Customer gives original 222 to contract delivery driver in a sealed envelope for delivery to distribution center.

4. Operations Manager or designee delivers faxed 222 to the vault.

5. Vault clerk fills order and files faxed 222. The order is held until the original 222 arrives at the distribution center and is compared to the order.

Preservation of Order Forms

(21 CFR 1305.13)

- The purchaser retains copy 3 (blue) of each filled order form. The purchaser also retains in his/her files all copies of each unaccepted or defective order form and any statements attached to them.

- The supplier retains copy 1 (brown) of each order form that has been filled.

- Order forms must be maintained separately from all other records of inspection for two years (as are all records of controlled substance transactions). If a purchaser has several registered locations, copy 3 (blue) of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to **(21 CFR 1305.06 (d))** must be kept at the registered location printed on the order form.

  Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

Unaccepted and Defective Order Forms
(21 CFR 1305.11)

Federal regulations applicable to the handling of such order forms are as follows:

- No Order Form shall be filled if it:

  (1) Is not complete, legible, or properly prepared, executed, or endorsed; or

  (2) Shows any alteration, erasure, or change of any description.

- If an Order Form cannot be filled for any reason under this section, the supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept the order; a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

- When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser in accordance with **21 CFR 1305.13**. A defective Order Form may not be corrected; it must be replaced by a new Order Form in order for the order to be filled.

- Any information which is pre-printed on the order form may not be altered in any way.

Pursuant to these regulations, order forms should be returned to the customer under the following circumstances:

- The writing is illegible or it is otherwise impossible to identify a customer's registration number, items specified or quantities, or there is improper execution or endorsement.
- There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.
- Signatures are omitted.
- Sixty days have elapsed from the date of execution by the purchaser.
- The last line completed is greater than the last line specified.

- The number of line items is greater than the total number of items specified.
- Customer voids a line.

Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

- The supplier's name, address, city, state, or zip code may be added when omitted by the customer.
- The supplier's address, city, state or zip code may be corrected.
- The date of the order may be added when omitted. Whenever possible, the postal date on the envelope should be used.
- It is permitted to add or change hydrochloride, sulfate, phosphate, ampules, tablets, etc. if the customer's order is correct in all respects except that it is specified in error; for example, specifies capsules and the product requested is properly designated and supplied in tablets.
- A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength stated may be corrected if the quantity of controlled substance is not increased in any way.
- Order forms may be accepted when the customer has sent all three copies of the form to the supplier, but the customer's copy must be forwarded to him in advance of the shipping product.
- Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.
- If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1 x 1000, may ship 10 x 100).
- Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.
- Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

A single item must be canceled for the following reasons, but the balance of the order may be shipped:

- If the number of packages, size of package, or strength has been altered by the person preparing the order form.

- If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.
- Strength is dittoed on the order form rather than designated.
- Strength is omitted (except trademark items when National Drug Code number is listed).
- Size of package incorrectly stated (quantity may be reduced).
- Size of package omitted.
- When a multiple item order is properly prepared and complete in all other respects but a single item has a non-correctable defect, this item may be canceled in lieu of returning the order form to the customer.

Refer to DEA Correspondences 6/29/92, 12/16/92, 7/28/94, and 9/14/95 for regulatory interpretations.

Cancellation and Voiding of Order Forms

(21 CFR 1305.15)

- A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier indicates the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for number of items shipped.

- A supplier may void part or all of an order form by notifying the purchaser in writing of such voiding on an **Order Form Rejection Notification (Form #6).** The supplier should keep a copy of the order form and the notification. The supplier indicates the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

- No cancellation or voiding permitted by this section affects in any way contract rights of either the purchaser of the supplier.

Narcotic Order Form Review

The DEA has established specific criteria for the acceptance of Narcotic Order Forms. To assure that the appropriate personnel receive continuous training with respect to these regulatory requirements, the previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations. Complete a **Narcotic Order Review Form (Form #7)** for any order forms that were processed in violation of DEA regulations. Discuss violations and the appropriate responsive action with personnel involved. File the Narcotic Order Review Form with a copy of the corresponding DEA Form 222.

Procedure for Endorsing Order Forms

(21 CFR 1305.10)

- An order form made out to any supplier who cannot fill all or part of the order within the time limitation set forth in 1305.09 may be endorsed to another supplier for filling. The endorsement is made only by the supplier to whom the order form was first made, states (in the space provided on the reverse sides of copies 1 (brown) and 2 (green) of the order form) the name and address of the second supplier, and is signed by the person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier fills the order if possible and if the supplier desires to do so, in accordance with **21 CFR 1305.09(b),(c) and (d)** including shipping all substances directly to the purchaser.

- Distribution made on endorsed forms is reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier records the name, address and registration number of the first supplier.

Lost or Stolen Order Forms

(21 CFR 1305.12)

- If a purchaser ascertains that an unfilled order form has been lost, the purchaser should execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered in the first order form were not received through loss of that order form. Copy 3 (blue) of the second order form and a copy of the statement are retained with copy 3 (blue) of the order form first executed. A copy of the statement is attached to copies 1 (brown) and 2 (green) of the second order form sent to the supplier. If the first order form subsequently is received by the supplier to whom it was directed, the supplier marks it as "Not accepted" and returns copies 1 (brown) and 2 (green) to the purchaser, who attaches it to copy 3 (blue) and the statement.
- Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person reports it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier should report the date or approximate date of receipt and the names and addresses of the purchasers. If an entire mailing envelope of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser should report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued. If any unused order form reported lost or stolen subsequently is recovered or found, the Registration Unit should be notified immediately.

Return of Unused Order Forms

(21 CFR 1305.14)

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked (pursuant to 21 CFR 1301.45 or 1301.46 of this chapter), the purchaser (or his/her executor) should return all unused order forms for controlled substances listed in Schedules I and II for which the purchaser is registered to the nearest DEA office.

REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When

Annual Inventory	To be taken on December 31
Initial Inventory	To be taken on the effective date that a substance becomes reportable
Transaction Reporting	Quarterly, or, with DEA permission, monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual **ARCOS OCR Form - DEA Form 333 - (Form #9).**

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on **Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10).** Reports must be submitted within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on **DEA Form 106** should also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA.

Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11)** in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on **ARCOS OCR Form 333.**

> *Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.*

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files **DEA Form 41. Refer to DEA Correspondence 8/12/94 for additional information.**

DEA Form 41 should also be used for documenting a liquid controlled substance loss when the container accidently breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. **Refer to DEA correspondence 11/17/97.**

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers should establish **written** criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish **reasonable** criteria based upon customer purchasing patterns and then to **adhere** to them in monitoring orders.

Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

STRUCTURAL SECURITY

Schedule II Controlled Substances
(21 CFR 1301.72)

Schedule II controlled substances are stored in a vault, the physical structure of which meets the following specifications or equivalent:

If grandfathered (a vault constructed before, or under construction on, September 1, 1971): substantial construction with a steel door and a combination or key lock.

A vault constructed after September 1, 1971: walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

The door and frame unit of the vault (GSA approved, Class V) conforms to the following specifications, or the equivalent:

- 30 man minutes against surreptitious entry;
- 10 man minutes against forced entry;
- 20 man hours against lock manipulation; and
- 20 man hours against radiological techniques.

Refer to DEA Correspondence 2/14/94 for a change in the specifications for the GSA Class V vault door.

DEA will also approve, on a case by case basis, UL listed Class M modular vaults for the storage of Schedule II controlled substances.

If operations require the vault to remain open for frequent access, then it must be equipped with a 'day gate' that is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove material in the morning and return material at night, and is always relocked immediately after use, a 'day gate' is not required.

Schedule III, IV, and V Controlled Substance Storage

DEA regulations **(21 CFR 1301.72(b))** provide that Schedule III through V controlled substances must be secured as follows:

- In a cage located within the building on the premises meeting the specifications in 1301.72(b)(4)(ii-iv) and Section 1301.72 (b)(3)(ii)(a)(b), which read as follows:

21 CFR 1031.72(b)(4):

- A cage, located within a building on the premises, meeting the following specifications:
- Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

  (a) At least one inch in diameter;

  (b) Set in concrete or installed with lag bolts that are pinned or brazed; and

  (c) Which are placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches;
- Having a mesh construction with openings of not more than two and one half inches across the square.
- Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height.
- Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b) (3)(ii)."

21 CFR 1301.72(b)(3):

- Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination

- The controlled substance section also provides:
  The track holding sliding 10-gauge steel gates in place is adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track surreptitiously.

  Alternate: Where swinging cage doors are installed, hinges are properly secured.